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09/822,261	04/02/2001	William A. Knaus	031672.0005	7290

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EXAMINER

PYZOCHA, MICHAEL J

ART UNIT	PAPER NUMBER
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2137

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/822,261

Applicant(s)

KNAUS ET AL.

Examiner

Michael Pyzocha

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 and 46-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 and 46-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 1-29, 46-75 are pending.

Election/Restrictions

2. Applicant's election without traverse of Group I in the reply filed on 02/25/2005 is acknowledged.

Claim Objections

3. The claim objections have been withdrawn based on the renumbering of the claims.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-25 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The term "at least some" in claim 1 is a relative term which renders the claim indefinite. The term "at least some" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of

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ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what the term "at least some" entitles. For the purpose of this examination "at least some" has been considered as "at least one."

Any claim not specifically addressed is rejected based upon its dependencies.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-3, 5-11, 16-17, 46-47, 51-53, 57-60, 63, 65, 68-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballantyne et al (U.S. 5,867,821) and further in view of Shear (U.S. 4,827,508).

As per claim 1, Ballantyne et al discloses a broad-band, computer-based networked system comprising: the medical records are obtained and electronically compiled from a plurality of sources (see figure 1); one or more medical records of the

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collection possess a characteristic of non-repudiation such that information contained within said medical records is verified as accurate and correct (see column 12 lines 48-55); the medical record of a person is transmissible in whole or in part only to that person and others authorized by that person (see column 8 lines 43-65); each medical record can be supplemented with additional information (see column 12 lines 24-31); and additional medical records for additional persons may be added to the collection (see column 12 lines 9-24); a secure access for allowing each person to access only their own medical record; and at least another secure access for allowing said others authorized to access only that person's medical record (see column 8 lines 14-65).

Ballantyne et al fails to disclose the collection of records being encrypted or secured when collected, accessed, inputted, viewed, integrated, or transmitted.

However, Shear teaches a collection of records being encrypted or secured when collected, accessed, inputted, viewed, integrated, or transmitted (see column 4 lines 65-68).

At the time of the invention it would have been obvious to a person of ordinary skill in the art to use Shear's method of encrypting records to encrypt Ballantyne et al' collection of medical records.

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Motivation to do so would have been to prevent excessive copying (see Shear column 5 lines 49-56).

As per claim 2, the modified Ballantyne et al and Shear system discloses the medical records are electronically complied by direct input or digital scanning of written information into a compute-readable format (see Ballantyne et al column 12 lines 9-47).

As per claim 3, the modified Ballantyne et al and Shear system discloses the sources are selected from the group consisting of hospitals, clinics, physician's offices, pharmacies and combinations thereof (see Ballantyne et al figure 1).

As per claim 5, the modified Ballantyne et al and Shear system discloses the medical record for each person contains one or more of: a table of contents, an index, a source notation for information contained within the medical record, an electronic search tool, annotations for errors, linked annotations for errors, treatment options, health care choices, verification standards, and news items relevant to the information in the medical record (see Ballantyne et al column 7 lines 7-65 and Shear column 11 lines 38-49).

As per claim 6, the modified Ballantyne et al and Shear system discloses the secure access and the another secure access

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comprise passwords or encryption keys (see Ballantyne et al figures 9A-9B and Shear column 5 lines 49-63).

As per claim 7, the modified Ballantyne et al and Shear system discloses the others authorized are selected from the group consisting of physicians, nurses, hospitals and health care institutions (see Ballantyne et al column 8 lines 20-30).

As per claim 8, the modified Ballantyne et al and Shear system discloses all of the medical records of the collection possess the characteristic of non-repudiation (see Ballantyne et al column 12 lines 48-55).

As per claim 9, the modified Ballantyne et al and Shear system discloses the non-repudiated medical record is primary for treatment of the patient to whom said non-repudiated medical record pertains (see Ballantyne et al column 12 lines 9-47).

As per claim 10, the modified Ballantyne et al and Shear system discloses each medical record is certified as accurate (see Ballantyne et al column 12 lines 9-47).

As per claim 11, the modified Ballantyne et al and Shear system discloses each certified medical record is certified as accurate by the patient, by the source from which said each medical record was obtained, by a system provider or by a combination thereof (see Ballantyne et al column 12 line 9-47).

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As per claim 16, the modified Ballantyne et al and Shear system discloses a fee which is assessed for each access to a medical record (see Shear column 3 lines 3-14).

As per claim 17, Ballantyne et al and Shear fail to disclose a maintenance fee. However, Official Notice is taken that it would have been obvious to one skilled in the art to assess a maintenance fee for the medical records. Motivation to do so would have been to pay for holding, correcting, and supplying the medical records.

As per claim 46, the modified Ballantyne et al and Shear system discloses a computer system for management of medical records that are not subject to repudiation comprising a database of medical records pertaining to one or more subjects; a receiver for receiving information pertaining to said medical records from one or more senders; a process for verifying that the information received is accurate and correct by at least vetting said information; a process for authorizing said senders and said additional receivers according to a set of rules wherein said set of rules is designated by said subjects; and a transmitter for transmitting at least a portion of said medical records to one or more additional receivers (see Ballantyne et al column 8 lines 9-65 and column 12 lines 9-47 and Shear column 6 lines 49-63).

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As per claim 47, the modified Ballantyne et al and Shear system discloses the database is a secure database (see Ballantyne et al column 8 lines 10-65).

As per claim 51, the modified Ballantyne et al and Shear system discloses the receiver is selected from the group consisting of: modem, cellular receiver, infrared receiver, Ethernet card, facsimile, cable modem, satellite receiver, optical, analog receiver, Internet hub, and web-server (see Ballantyne et al column 9 lines 1-15).

As per claim 52, the modified Ballantyne et al and Shear system discloses the transmitter is selected from the group consisting of: modem, cellular receiver, infrared receiver, Ethernet card, facsimile, cable modem, satellite receiver, optical, analog receiver, Internet hub, and web-server (see Ballantyne et al column 4 lines 65-67).

As per claim 53, the modified Ballantyne et al and Shear system discloses the process of authorizing comprises public key encryption, digital signatures, biometrics, certificate authorities, or user passwords (see figures 9A-9B, 11C and Shear column 5 lines 49-63).

As per claim 57, the modified Ballantyne et al and Shear system discloses the database is administer by a service

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provider other than said subjects, senders, and receivers (see Shear column 4 lines 9-20).

As per claim 59, the modified Ballantyne et al and Shear system discloses the medical records are owned by said subjects (see column 7 line 66 through column 8 line 9).

As per claim 60, the modified Ballantyne et al and Shear system discloses the collection being encrypted and secured (see Shear column 4 lines 65-68).

As per claim 63, the modified Ballantyne et al and Shear system discloses the information contained within the medical records is verified as accurate and correct as to accuracy of transcription (see Ballantyne et al column 12 lines 48-55).

As per claim 65, the modified Ballantyne et al and Shear system discloses the claimed limitations as similarly applied to claim 1.

As per claim 68, the modified Ballantyne et al and Shear system discloses the information contained within the medical records is verified as accurate and correct as to accuracy of transcription (see Ballantyne et al column 12 lines 48-55).

As per claim 69, the modified Ballantyne et al and Shear system discloses the medical record is primary for treatment of the patient to whom said medical record pertains (see Ballantyne et al column 12 lines 9-47).

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As per claim 70, the modified Ballantyne et al and Shear system discloses all of the medical records of the collection possess the characteristic of non-repudiation (see Ballantyne et al column 12 lines 48-55).

As per claim 71, the modified Ballantyne et al and Shear system discloses the non-repudiated medical record is primary for treatment of the patient to whom said non-repudiated medical record pertains (see Ballantyne et al column 12 lines 9-47).

As per claim 72, the modified Ballantyne et al and Shear system discloses each medical record is certified as accurate (see Ballantyne et al column 12 lines 9-47).

As per claim 73, the modified Ballantyne et al and Shear system discloses each certified medical record is certified as accurate by the patient, by the source from which said each medical record was obtained, by a system provider or by a combination thereof (see Ballantyne et al column 12 line 9-47).

9. Claims 20-22, 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker ("PCASSO: A Model for Safe Use of the Internet in Healthcare") and further in view of Ballantyne et al.

As per claim 20, Baker discloses a broad-band computer-based networked system for individual control and management of electronic medical records comprising a plurality of medical

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records representing a plurality of persons wherein said plurality complies with a federal standard of privacy and security (see Baker pages 34-35).

Baker fails to disclose at least one medical record of the plurality is not subject to repudiation.

However, Ballantyne et al teaches a medical record not subject to repudiation (see column 12 lines 48-55 where the signature ensures non-repudiation).

At the time of the invention it would have been obvious to a person of ordinary skill in the art to use Ballantyne et al's method of non-repudiation in Baker's medical record distribution system.

Motivation to do so would have been for authorization to change records (see Ballantyne et al column 12 lines 48-55).

As per claim 21, the modified Baker and Ballantyne et al system discloses allowing for certification of said medical records (see Ballantyne et al column 12 lines 48-55).

As per claim 22, the modified Baker and Ballantyne et al system discloses the certification represents a predetermined degree of completeness, accuracy or both to said medical records (see Ballantyne et al column 12 lines 48-55).

As per claim 26, the modified Baker and Ballantyne et al system discloses the non-repudiated medical record is primary

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for treatment of the patient to whom said non-repudiated medical record pertains (see Ballantyne et al column 12 lines 9-47).

As per claims 27-29 and 48-50, the modified Ballantyne et al, Shear, and Baker system discloses the collection complies with privacy and security standards (see Bates page 34 column 2).

10. Claims 4, 12-15, 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Ballantyne et al and Shear system as applied to claims 1, 46 above, and further in view of Baker ("PCASSO: A Model for Safe Use of the Internet in Healthcare").

As per claim 4, the modified Ballantyne et al and Shear system fails to disclose medical records being transmittable through the Internet.

However, Baker teaches medical records being transmittable through the Internet (see page 34 column 1).

At the time of the invention it would have been obvious to a person of ordinary skill in the art to use Baker's method of transmitting medical records in the medical record distribution system of Ballantyne et al and Shear.

Motivation to do so would have been that the Internet can support an information access and distribution model (see Baker page 34 column 1).

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As per claim 12, the modified Ballantyne et al, Shear, and Baker system discloses the collection comprises medical records of more than 100,000 persons (see Baker page 34 column 3).

As per claims 13-15 and 48-50, the modified Ballantyne et al, Shear, and Baker system discloses the collection complies with privacy and security standards (see Bates page 34 column 2).

11. Claims 18-19, 54-56, 61-62, 64, 66-67, 74-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Ballantyne et al and Shear system as applied to claims 1 and 46 above, and further in view of Arpeggio ("Checking Database Integrity").

As per claims 18-19, the modified Ballantyne et al and Shear system fails to disclose vetted medical records containing one or more of: corrections of incorrect information, notations of incorrect information, notations of anomalies, linking of errors, linking of anomalies, notation of discrepancies, linking of discrepancies, and combinations thereof.

However, Arpeggio teaches such vetted records (see pages 1-4).

At the time of the invention it would have been obvious to a person of ordinary skill in the art to use Arpeggio's vetted

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records in the modified medical record distribution system of Ballantyne et al and Shear.

Motivation to do so would have been to help find and correct database integrity problems (see Arpeggio page 1).

As per claim 54, the modified Ballantyne et al, Shear and Arpeggio system discloses the process of verifying results in an improved accuracy or correctness of at least a portion of the information received from said one or more senders (see Arpeggio pages 1-4).

As per claim 55, the modified Ballantyne et al, Shear and Arpeggio system discloses the non-repudiated medical records are primary for treatment of said subjects (see Ballantyne et al column 12 lines 9-47).

As per claim 56, the modified Ballantyne et al, Shear and Arpeggio system discloses an integrator for reception, display, analysis and modification of said medical records available to be performed on a plurality of systems of health case providers, payers, clearinghouses, or oversight agencies (see Arpeggio pages 1-4).

As per claims 61-62, 64, 66-67, 74-75, the modified Ballantyne et al, Shear and Arpeggio system discloses these limitations as applied to above claims (where the vetting is the

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rule-based process for verifying the records as accurate and correct).

12. Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Baker and Ballantyne et al system as applied to claim 20 above, and further in view of Arpeggio.

As per claim 23, the modified Baker and Ballantyne et al system fails to disclose vetting of said medical records.

However, Arpeggio teaches vetting of records (see pages 1-4).

At the time of the invention it would have been obvious to a person of ordinary skill in the art to use Arpeggio's vetted records in the modified medical record distribution system of Baker and Ballantyne et al.

Motivation to do so would have been to help find and correct database integrity problems (see Arpeggio page 1).

As per claim 24, the modified Baker, Ballantyne et al and Arpeggio system discloses the vetted medical records have been reviewed and corrected or annotated for errors, discrepancies and anomalies (see Arpeggio pages 1-4).

As per claim 25, the modified Baker, Ballantyne et al and Arpeggio system discloses the accuracy and correctness of at least one medical record of the plurality of medical records is

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better than exists at a source site from which the medical record was obtained (see Arpeggio pages 1-4).

Response to Arguments

13. Applicant's arguments filed 02/25/2005 have been fully considered but they are not persuasive. Applicant argues: Ballantyne is not a patient-based medical record system where a patient doesn't have control or manage one's own medical records; Ballantyne's authenticated signature does not impart non-repudiation; Ballantyne does not suggest medical records that are primary for treatment; Ballantyne does not suggest the medical records are owned by the subjects because the patients must request the information from a database; Baker cannot be combined with Ballantyne and Shear; and Arpeggio's vetting is not the vetting of the invention.

Ballantyne is a patient-based medical record system where it is a system containing patient-based medical records. The added argument regarding the patient controlling the system is not a claimed limitation and therefore is not considered.

Ballantyne's authenticated signature imparts non-repudiation because no changes to the record can be made with the authorized signature, which holds the integrity and

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authenticity of the document so to hold the accuracy and correctness of the document.

Ballantyne does suggest medical records that are primary for treatment as cited in column 12 lines 9-47 the medical records are retrieved when a patient is admitted, which is before any treatment is done.

Ballantyne suggests the subjects own the medical records because the patients have access to all of their records and doctors can be limited access. Just because they are held in a database remote from the subject does not mean the subject does not own them.

Baker can be combined with Ballantyne and Shear because Ballantyne and Shear relate to medical records stored in a database and metering a database so creating secure access to a database, as in Baker, is analogous art.

Arpeggio's vetting may not be the vetting of the invention however; the claimed limitation does not have the cited limitations from the specification therefore Arpeggio reads on the claimed limitation of vetting.

Conclusion

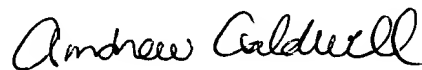
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael

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Pyzocha whose telephone number is (571) 272-3875. The examiner can normally be reached on 7:00am - 4:30pm first Fridays of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Caldwell can be reached on (571) 272-3868. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MJP

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